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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/052,832	01/15/2002	Gregory R. Mundy	432722002612	3485

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EXAMINER	
GITOMER, RALPH J	

ART UNIT	PAPER NUMBER
1627	4

DATE MAILED: 04/29/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
10/052,832	Mundy et al.
Examiner	**Art Unit**
Ralph Gitomer	1627

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jan 15, 2002* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *25 and 45-70* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *25 and 45-70* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 25, 45-70 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 7-13 of copending Application No. 09/361,775. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications claim PSI for the same function but the present application broadly includes additional compounds.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 25, 45-70 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for PSI, does not reasonably provide enablement for a compound that inhibits proteasomal activity, inhibits the chymotrypsin like activity of the proteasome. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

On page 27 of the present specification, PSI is defined as N-carbobenzoyl-Ile-Glu-(OtBu)-Ala-Leu-CHO. On page 34 high throughput screening is mentioned but does not state for what the compounds were screened. On page 43 Example 10 shows effects of PSI on subcutaneous tissue of the scalp of mice. Example 11 is directed to cultured skin from mice. Example 12 is directed to inducing anagen in mice with the drug injected into the site of interest directly. Example 13 is directed to topical PSI in mice. All of the examples include no meaningful or statistically significant data regarding its effects especially as claimed in present claims 64, 68, 70 and others. Please specifically point out in the specification complete written description for all the claimed features.

The entire scope of the claims has not been enabled because:
1. Quantity of experimentation necessary would be undue because of the large proportion of inoperative compounds claimed.

2. Amount of direction or guidance presented is insufficient to predict which substances encompassed by the claims would work.
3. Presence of working examples are only for specific substances and extension to other compounds has not been specifically taught or suggested.
4. The nature of the invention is complex and unpredictable.
5. State of the prior art indicates that most related substances are not effective for the claimed functions.
6. Level of predictability of the art is very unpredictable.
7. Breadth of the claims encompasses an innumerable number of compounds.
8. The level of one of ordinary skill in this art is variable.
In re Wands, 858 F.2d 731, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)

Claims 25, 45-70 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in all occurrences.

In claim 25 the compound is described in functional terms only, not what the structure or name of the compound may be which is indefinite. In claim 60 the names should be spelled out.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 25, 45-59, 61-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murase.

Murase (WO97/35618) entitled ※Dermatologic Preparation※ teaches in the abstract, an NfkB activation inhibitor which prevents degeneration or breakdown of corium constituents for treating skin conditions.

The claims differ from Murase in that they are directed to stimulating hair growth specifically.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to stimulate hair growth with the method of Murase which prevents degeneration of corium constituents because degeneration of the corium would be detrimental to hair growth.

Claim 60 is rejected under 35 U.S.C. 103(a) as being unpatentable over Murase as applied to claims 25, 45-59, 61-70 above, and further in view of Fenteany.

The teachings of Murase and their applicability to the instant invention have been discussed above.

The claim differs from Murase in that it is directed to lactacystin and other compounds.

Fenteany (6,147,223) entitled ▒Lactacystin Analogs▒ with a 102(e) date of 4/12/95, teaches in column 1 lactacystin and analogs and proteasome dependent pathways. In column 11 lines 38-47, lactacystin and analogs are selective for proteasome. See column 63 Examples 5 and 6.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ lactacystin or a peptidyl aldehyde as a proteasomal inhibitor in the method of Murase because Fenteany teaches that lactacystin is a proteasomal inhibitor.

The title of the invention is not aptly descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The Abstract of the Disclosure is objected to because it is not directed to the claimed invention. Correction is required. See M.P.E.P. § 608.01(b).

The disclosure is objected to because of the following informalities: On page 4 line 14 and all occurrences, referring to patent applications which have not been published is improper. Appropriate correction is required.

The following prior art pertinent to applicant's disclosure is made of record and not relied upon:

Dussourd (WO 97/18239) teaches peptide conjugates including aldehydes for treating hair loss.

Faustman (WO 99/43346) teaches NFkB activity alterations.

Wojcik (Eur J of Cell Bio) teaches PSI and proteasome activity.

Figueiredo-Pereira (J of Neurochemistry) teaches proteasome inhibitors.

Vinitsky (J of Bio Chem) teaches proteasome inhibitors.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (703) 308-0732. The examiner can normally be reached on Tuesday-Friday from 8:00 am - 5:00 pm. The examiner can also be reached on alternate Mondays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat can be reached on (703) 308-2439. The fax phone number for this Art Unit is (703) 308-4556. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235. For 24 hour access to patent application information 7 days per week, or for filing applications electronically, please visit our website at www.uspto.gov and click on the button ※Patent Electronic Business Center※ for more information.

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